



FEB 27 2012

K113545

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510(k) SUMMARY

Date Prepared

November 30, 2011

**Submitter's Name
and Address:**

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Contact Person

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**Name of Medical
Device**

Classification Name: Electrosurgical cutting and coagulation device and accessories: 21 CFR 878.4400

Common/Usual Name: Electrosurgical cutting and coagulation device and accessories: Arthroscope

Proprietary Name: VAPR® VUE™ Radiofrequency System
VAPR III Electrode Surgical System
VAPR II Electrode Surgical System
P90 Electrode
CP90 Electrode
CP90 Electrode with Handcontrol
LDS Electrode
LPS Electrode

FDA Classification: II

FDA product code: GEI

Device Description

The VAPR system is an electro-surgical system that utilizes bipolar technology specifically designed to provide a range of arthroscopic surgical treatments including soft tissue ablation, contouring, cutting and coagulation and temperature control. The VAPR system includes a generator, electrodes which facilitate access and control the delivery of energy to the joint space, and accessories such as a footswitch and electrodes.

Description of Change

This premarket notification is submitted to add HIP arthroscopy to the indication for use for the VAPR Generators and VAPR Electrodes listed in this section.

As a result, the Instructions for Use (IFU) will be updated to add the hip indication.

In addition the following modifications have also been made to the VAPR system Manuals and Electrode IFU's:

- Removing Arthroscopic joint surgery examples from VAPR VUE, VAPR II and VAPR III manuals.
- Add an electrode shaft bending caution.

There have been no changes to the devices which are the subject of this submission. The purpose of this submission is to evaluate the performance testing to support the addition of hip indication.

Indications for Use

VAPR VUE Radiofrequency system

The Mitek VAPR VUE Radiofrequency System is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

VAPR II Electro-surgical system

The Mitek VAPR II Electrode System, when used with a VAPR™ Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

VAPR 3 Electro-surgical system

The VAPR 3 Electrode System, when used with a VAPR™ Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

VAPR CoolPluse Electrodes

The DePuy Mitek VAPR Electrodes for use with the VAPR VUE Radiofrequency System are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

VAPR Suction Electrodes (P90, CP90, CP90 with Handcontrol)

The DePuy Mitek VAPR Electrodes for use with all VAPR Electrosurgical Systems are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

VAPR Suction Electrodes (LDS and LPS Electrode)

The VAPR LD and LP Suction Electrodes, when used with the VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

Substantial Equivalence

With the addition of the Hip indication, the VAPR Systems and electrodes which are the subject of this submission will have the same indication as the following electrodes currently on the market:

- Serfas RF System: K041810

Safety and Performance

Verification and Validation of the VAPR Electrodes included performance testing to demonstrate that the device is appropriate for hip arthroscopy. A summary of testing is provided in Table 1.

Table 1

Testing	Results
Device Insertion	Pass: No visible cracks or missing portions at the distal tip of the electrodes.
Shaft Bending	Pass: No visible splitting of heatshrink after one cycle of bending and straightening of the electrode handle and shaft.
Active Tip Engagement	Pass: The electrodes withstood with no breakage at the active tip.

Clinical Testing

No clinical studies are required to demonstrate safety and efficacy of the device in support of an application for premarket clearance. The VAPR System and Electrodes, when used for hip arthroscopic surgeries, do not differ from the predicate devices in fundamental scientific technology.

Conclusion

Results of safety and performance and testing have demonstrated that the modified device is suitable for its intended use.

Based on the indications for use and fundamental scientific technology, the VAPR System, along with the VAPR Electrodes are shown to be appropriate for arthroscopy of the hip as well as substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

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Depuy Mitek, a Johnson & Johnson Company
% Ms. Susan Kagan
Project Manager, Regulatory Affairs
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Raynham, Massachusetts 02767

Re: K113545

Trade/Device Name: VAPR VUE Radiofrequency System
VAPR II Electrosurgical System
VAPR III Electrosurgical System
VAPR CoolPulse Electrodes (CP90, CP90 with Handcontrol)
VAPR Suction Electrodes (PD90, LDS, and LPS Electrode)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI, HRX

Dated: November 30, 2011

Received: December 1, 2011

Dear Ms. Kagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic
and Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known):

Device Name: **VAPR Generator**

Indications for Use:

VAPR VUE Radiofrequency system

The Mitek VAPR VUE Radiofrequency System is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery.

VAPR II Electrosurgical system

The Mitek VAPR II Electrode System, when used with a VAPR™ Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery.

VAPR III Electrosurgical system

The VAPR 3 Electrode System, when used with a VAPR™ Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery.

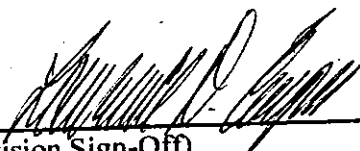
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Indications for Use

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510(k) Number (if known):

Device Name: **VAPR Electrodes**

Indications for Use:

VAPR CoolPulse Electrodes (CP90, CP90 with Handcontrol)

The DePuy Mitek VAPR Electrodes for use with the VAPR VUE Radiofrequency System are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

VAPR Suction Electrodes (P90, LDS and LPS Electrode)

The VAPR LD and LP Suction Electrodes, when used with the VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissues, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, hip, ankle, elbow and wrist.

Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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